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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

New Compounds for Treating or Preventing Obesity

Description of Technology: Available for licensing are new compounds developed for the treatment or prevention of obesity. The compounds act to block the absorption of dietary fats in the gut by interfering with signaling through the farnesoid X receptor. There is correlative evidence that inhibition of the farnesoid X receptor can reduce obesity resulting from high fat-based diets. While many farnesoid X receptor agonists are known, until now there have been no known therapeutic agents that can inhibit this receptor.

Also available for licensing are methods of synthesizing the compounds and methods of using the compounds to treat or prevent obesity.

Potential Commercial Applications:

• Pharmaceutical treatments for obesity

• Pharmaceutical agents to reduce weight gain

Competitive Advantages:

• There are no known therapeutic agents to inhibit the farnesoid X receptor; thus, agents developed from the present technology could be first-to-market.

• Compounds stay in the intestine and are not toxic.

Development Stage:

• Early-stage

• In vitro data available

• In vivo data available (animal)

Inventors: Frank Gonzalez, Fei Li, Changtao Jiang, James Mitchell (all of NCI)

Intellectual Property: HHS Reference No. E-508-2013/0 – US Provisional Application No. 61/861,109 filed 01 August 2013

Licensing Contact: Patrick McCue, Ph.D.; 301-435-5560; mccuepat@mail.nih.gov

Chimeric Antigen Receptors to CD276 (B7-H3) for Treatment of Cancer

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins consisting of an antibody binding fragment fused to protein signaling domains. When CARs are expressed in T-cells, the T-cells become cytotoxic towards cells expressing the proteins that the CAR recognizes. By developing a CAR that is specific for a cell surface protein that is selectively expressed on diseased cells, it is possible to selectively target those cells for destruction, thereby treating the disease.

Solid tumors are typically treated with a non-specific approach of surgical resection, followed by chemotherapy or radiation therapy. Unfortunately, such an approach is traumatic for the patient, and leads to numerous side-effects. This suggests that a more specific approach to treating solid tumors is needed. CD276 (B7-H3) is a tumor-associated antigen that is expressed on several solid tumors, making it a promising therapeutic target. This technology concerns the generation of three high-affinity CARs (CD276.1, CD276.6 and CD276.17) that target CD276. These CARs can potentially be used in the treatment of cancers associated with CD276 expression.

Potential Commercial Applications:

• Treatment of diseases associated with increased or preferential expression of CD276.

• Specific diseases include neuroblastoma, Ewing's sarcoma, rhabdomyosarcoma, and prostate, ovarian, colorectal, and lung cancers.

Competitive Advantages:

• High affinity of the CARs increases the likelihood of successful targeting.

• Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients.

Development Stage:

• Early-stage

• In vitro data available

Inventors: Rimas J. Orentas, et al. (NCI)

Intellectual Property: HHS Reference No. E-104-2013/0-US-01 – US Provisional Patent Application No. 61/805,001 filed 25 March 2013

Related Technologies:

• HHS Reference No. E-291-2012/0 – International Patent Application No. PCT/US2013/060332 filed 18 September 2013; "M971 Chimeric Antigen Receptors," Orentas R, et al.

• HHS Reference No. E-007-2014/0 – US Provisional Patent Application No. 61/865,845 filed 06 November 2013; "ALK Specific Chimeric Antigen Receptors," Orentas R, Mackall C.

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov

Collaborative Research Opportunity: The Pediatric Oncology Branch, CCR, NCI, is seeking statements of capability or interest from parties interested in collaborative

research to further develop, evaluate or commercialize chimeric antigen receptors (CARs) specific for tumor-expressed CD276 (B7-H3). For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Bispecific Antibodies to Target Latent HIV-1 Infection

Description of Technology: The invention describes bispecific antibodies designed to kill latently HIV-1 infected T cells. It is thought that such bispecific antibodies will reduce or eliminate the pool of HIV-1 infected cells, contributing to functional cure. The antibody constructs comprise an HIV Env-binding fragment of a broadly neutralizing antibody linked to an anti-CD3 single chain variable fragment (scFv). One embodiment is a VRC01 scFv linked to the anti-CD3 scFv . Other embodiments comprise Fab fragments of VRC07 or 10E8 antibodies linked to the anti-CD3 scFv. The bispecific antibody simultaneously stimulates infected cells to express gp120, instructs cytotoxic T cells to kill these cells, and neutralizes extraneous viral particles.

Potential Commercial Applications: Immunotherapy of HAART-suppressed HIV-1 infection.

Competitive Advantages:

• Immunotherapy targets latently infected cells harboring virus resistant to HAART.

• Broadly neutralizing antibody fragment neutralizes extraneous viral particles.

Development Stage:

• Pre-clinical

• In vivo data available (animal)

Inventors: Gary J. Nabel, Xiaoti Guo, Amarenda Pegu, Zhi-yong Yang (all of NIAID)

Intellectual Property:

• HHS Reference No. E-071-2012/0 – US Application No. 61/638,437 filed 25 April 2012

• HHS Reference No. E-071-2012/1 – PCT Application No. PCT/US2013/038214 filed 25 April 2013, which published as WO 2013/163427 on 31 October 2013

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301-435-4507; ThalhamC@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Vaccine Research Center, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize HIV-1 bispecific antibodies. For collaboration opportunities, please contact Barry Buchbinder, Ph.D. at 301-594-1696.

Dated: January 2, 2014.

Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,
Office of Technology Transfer,
National Institutes of Health.

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